UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NOVARTIS PHARMA AG, *Plaintiff*, v. INCYTE CORPORATION, *Defendant*.	Case No. 20-cv-00400-GHW Hon. Gregory H. Woods

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF INCYTE CORPORATION'S MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

INTRODUCTION

As set forth in Incyte's opening brief (Dkt. 35 "Mot."), the parties' Agreement called for a 50% step-down in the royalty rates paid to Novartis on Incyte's U.S. sales of JAKAFI® beginning in 2019, after Regulatory Exclusivity ended with the expiration of ODE for the MF indication in November 2018. Novartis's opposition (Dkt. 42, "Opp.") fails to refute that reality.[1]

The lack of textual support for Novartis's claims is clear from its reliance on non-textual arguments. For example, Novartis complains that applying the Agreement's plain terms would "eviscerate Novartis' return on its investment." This is untrue. Novartis generates annual sales of almost $1 billion in the Novartis territory. (Dkt. 35 at 10.). But even if Novartis's profits were jeopardized by the step-down, that is no reason for this Court to re-write the Agreement. Novartis also implores the Court to adopt its untenable interpretations of the Agreement's text based on what Novartis calls "commercial logic," but that logic is fallacious. Novartis emphasizes that the Agreement was intended to create a collaborative relationship—a generality with which Incyte agrees—but that collaborative relationship explicitly provides for the step-down that Incyte invoked. Collaboration does not compel any particular allocation of U.S. sales revenue. Novartis also contends that it should continue to receive the higher royalty rate and prolong the Royalty Term as long as JAKAFI® retains patent protection from generic competition. But it is perfectly commercially logical for parties to agree—as they did here—that Incyte would pay a higher royalty if Novartis obtained patents to protect JAKAFI®, but not when Novartis failed to obtain any patents. Novartis's assertion that the royalty rate should remain unchanged while JAKAFI® retains regulatory rights to exclude competition as to some but not all indications ignores that expiry of

[1] All abbreviated terms defined in Incyte's opening brief are used herein, with the exception of "Novartis," which refers to Novartis Pharma AG given the case caption change after the merger of Novartis International Pharmaceutical AG into Novartis Pharma AG. *See* Dkt. 45.

ODE for the MF indication ended Incyte's regulatory right to exclude third-party competitors.

This case presents the Court with two narrow questions of interpretation of royalty terms that—as Novartis concedes in the first paragraph of its complaint—are unambiguous. Novartis and Incyte are sophisticated commercial actors, and New York contract law is clear both that such parties are held to the text of their agreements and that interpretation of unambiguous contract terms is a matter of law that may be decided on a motion to dismiss. Neither the commercial success of JAKAFI® nor Novartis's regret that it did not negotiate for a provision that would provide it with higher royalties for a longer term is any basis to re-write the parties' deal.

ARGUMENT

Novartis leans on the pleading rules of *Twombly*/*Iqbal*, arguing (Opp. 10-12) that its "interpretation" of the Agreement at least "satisfies the plausibility standard." This is a distraction. The only material facts—the absence of Novartis-owned U.S. patents covering ruxolitinib and the expiration of ODE for the MF indication—were pleaded by Novartis (Compl. ¶¶ 26, 29) and are undisputed. Plausibility becomes relevant in the context of extrinsic evidence needed to interpret an ambiguous contract and the cases cited by Novartis illustrate this. *See* Mot. 12; *Wilson v. Poughkeepsie City Sch. Dist.*, 147 A.D.3d 1112, 1114 (2d Dep't 2017).[2] For the reasons herein,

[2] Every case Novartis cites in arguing that it meets the *Twombly*/*Iqbal* pleading standard is thus irrelevant, because each involved use of extrinsic evidence to interpret an *ambiguous* contract. *See Columbia Cas. Co. v. Neighborhood Risk Mgmt. Corp.*, 2015 WL 3999192, at *9 (S.D.N.Y. June 29, 2015) (where "contract language is ambiguous" and movant "d[id] not argue that, should the Court find the contract to be ambiguous, its motion to dismiss nevertheless should succeed," denying motion to dismiss); *Dresser-Rand Co. v. Ingersoll Rand Co.*, 2019 WL 1434575, at *5 (S.D.N.Y. Mar. 29, 2019) (denying motion to dismiss on same basis, citing *Columbia Casualty Co.*); *Clarendon Nat'l Ins. Co. v. Health Plan Adm'rs*, 2009 WL 3053736, at *2 (S.D.N.Y. Sept. 24, 2009) ("A claim that is predicated on a materially ambiguous contract term is not dismissible on the pleadings."); *American Bldg. Maint. Co. of N.Y. v. Acme Prop. Servs., Inc. et al.*, 515 F. Supp. 2d 298, 311 (N.D.N.Y. Aug. 29, 2007) ("There is ambiguity in the contracts…."). Novartis misleadingly quotes (Opp. 11) *Citibank, N.A. v. Jacobsen*'s statement that "[t]he Court need not decide now as between whether the term is ambiguous or unambiguous in its inclusion of the loan repayment obligation," but the court's denial of a motion to dismiss was based on its finding of a

Novartis's arguments establish no such ambiguity, and the unambiguous text of the Agreement compels dismissal as a matter of law.

I. No "Licensed Patent Rights" Cover U.S. JAKAFI® Sales Under Section 8.3(c)(i)

Novartis concedes that the ***only*** patents that cover JAKAFI® are Incyte's own U.S. patents. Its arguments that these patents suffice to delay the royalty step-down are baseless.

A. Incyte's Royalty Obligations Are Not Affected By Incyte's Own Patents

Novartis asserts (Opp. 12) that "Licensed Patent Rights encompasses ***both*** 'Patent Rights licensed to Novartis hereunder' and 'Patent Rights Licensed to Incyte hereunder,'" and that the term "encompasses all Patent Rights ***licensed by either party to the other***." This position intentionally omits critical words in the definition of "Licensed Patent Rights," and ignores the various ways in which Patent Rights are addressed in the Agreement.

Incyte's royalty obligations for U.S. sales of JAKAFI® are explicitly limited to patents only to the extent that JAKAFI® is subject to (*i.e.*, "Covered by a Valid Claim of") "Licensed Patent Rights." Novartis cannot dispute that Section 8.3(c)(i) uses the narrowest of the Agreement's definitions—the definition of "Licensed Patent Rights" that is set forth in Section 1.67 serves the sole purpose of defining the parties' respective royalty obligations. That definition describes two cases—"with respect to the Patent Rights licensed to Novartis hereunder, the Incyte Patent Rights and with respect to the Patent Rights licensed to Incyte hereunder, the Novartis Patent Rights."[3]

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material ambiguity. 2020 WL 1503229, at *7 (S.D.N.Y. Mar. 30, 2020) ("[T]he Court finds that Guaranteed Obligation does not unambiguously exclude the obligation to guaranty…"). Incyte's reference to the Agreement's integration clause is not, as Novartis contends (Opp. 11), a "red herring." "[T]he purpose of an integration clause is to require full application of the parol evidence rule…." *Dujardin v. Liberty Media Corp.*, 359 F. Supp. 2d 337, 356 (S.D.N.Y. 2005) (quotation marks omitted). The cases Novartis cites (Opp. 11 n.7) hold only that if there is an ambiguity in a contract, the parol evidence rule permits consideration of extrinsic evidence. Here, there is none.

[3] Novartis argues (Opp. 16) that there is some "illogic" in requiring Novartis to license patents to Incyte, because it would not be profitable for Novartis to "have undertaken all the burden [of developing new patents] and then only realize, at most, the 5% royalty from those U.S. sales."

Novartis fails to explain why the parties would create a definition of "Licensed Patent Rights" using words of limitation if they had intended the result advocated by Novartis—a result that would have been easily achieved by using either the broad phrase "Patent Rights" or phrase "Incyte Patent Rights and Novartis Patent Rights" in Section 8.3(c)(i). As explained in Incyte's opening brief (Mot. 15), the use of that particular defined term, uniquely found only in royalty section 8.3(c), rather than one of the broader definitions, makes clear that the Patent Rights relevant to each party's royalty obligations are those that the royalty paying party licensed from the royalty receiving party—*i.e.*, as applicable here, any "Novartis Patent Rights." Any other conclusion reads words out of Section 1.67 and treats it as if the parties had agreed that "Licensed Patent Rights means … the Incyte Patent Rights and … the Novartis Patent Rights." That is improper. *See Givati v. Air Techniques, Inc.*, 104 A.D.3d 644, 645 (2d Dep't 2013) ("[A] court should not read a contract so as to render any term, phrase, or provision meaningless or superfluous.").

As Incyte noted in its opening brief (Mot. 15 n.7), moreover, giving effect to the two-part structure of the definition of "Licensed Patent Rights" is consistent with the Agreement's definition of "Covering" and "Covered." "Covering," as defined in section 1.23, " means that, ***but for a license granted*** to a Person under a Valid Claim included in the Patent Rights under which such license is granted, the Development, manufacture, Commercialization and/or other use of such product or the practice of such technology, process or method, by such Person would infringe such Valid Claim." Agreement § 1.23. Incyte is obligated to pay royalties under Section 8.3(b) on a "JAK Licensed Product-by-JAK Licensed Product basis," and "such JAK Licensed Product"

This math does not check out because—if it had obtained U.S. patents covering JAKAFI®—those patents would have both prevented Incyte's royalty rate from stepping down and extended the term during which Incyte was required to pay royalties. Further, in all likelihood, any such patented inventions would have been for the primary purpose of protecting Novartis's sales of ruxolitinib outside the U.S., with U.S. patent filings subsequently or simultaneously made at little cost.

in this case means JAKAFI®. But Incyte does not need a license from Novartis or anyone else to manufacture, market, and sell JAKAFI® in the U.S.

Ignoring both the two-part structure of the definition of "Licensed Patent Rights" and the fact that JAKAFI® is not "Covered" by Incyte's patents, Novartis asserts that Incyte's patents satisfy the condition set forth in Section 8.3(c)(i) for extending the tenor and maintaining the full quantum of Incyte's royalty obligations to Novartis because Incyte granted Novartis a limited license under Section 2.1(b). That limited license allows Novartis to "research, Develop, make and have made" its own ruxolitinib products in the U.S., but only for the purpose of facilitating Novartis's ability to sell ruxolitinib in Novartis's foreign territories. Opp. 6 (admitting that Novartis does not have a license to sell ruxolitinib in the U.S.). This argument cannot be reconciled with the two-part structure of Section 1.67 or with the parties' decision to create a special-purpose definition to define the patent rights that would affect their respective royalty obligations under Section 8.3.[4] Nor can it be squared with the fact that none of the activities licensed to Novartis—research, development, and manufacturing—generate revenues on which royalties would be paid.

B. The Plain Meaning Of Sections 1.67 And 8.3(c)(i) Is Commercially Logical

Novartis's contends (Opp. 15-17) that application of the step-down while Incyte's patents exist "defies commercial logic." That is not so. Novartis's position contravenes commercial logic.

The Agreement's step-down provision is, of course, not a provision that operates for

[4] Novartis also erroneously argues (Opp. 13) that, in Section 8.3(c)(i), "the word 'any' modif[ying] 'Valid Claim of Licensed Patent Rights'" means that "'any' Patent Rights licensed under the Agreement, including if Licensed outside the geography of sale, satisfies the meaning of the term." The error of this reasoning is that the Agreement does not state "any Patent Rights," as Novartis suggests (misleadingly omitting the critical word "Licensed" that distinguishes Licensed Patent Rights from the broader defined term, "Patent Rights"). Rather, "any" modifies "Valid Claim." The import of the word "any" in this sentence is simply that if a patent includes multiple patent claims, any one of those claims that remains valid (*i.e.*, has not expired or been invalidated) and Covers JAKAFI® will serve to delay the step down under Section 8.3(c)(i).

Incyte's sole benefit. It operates mutually, governing both parties' royalty obligations. That a royalty paying party would pay higher royalties for a longer time if the product on which it paying royalties is Covered by a Valid Claim of one of the royalty receiving party's patents is perfectly logical. The royalty paying party would need a license, and also would enjoy the protection against competition afforded by the royalty receiving party's patents. And such a rule maximizes the incentives for both parties to increase their patent portfolios—to their mutual benefit. The same cannot be said however, for the reading that Novartis advocates. Under that rule, a royalty paying party's expansion of its own patent portfolio would result in that party's higher royalties for a longer term—thereby reducing the incentive to acquire additional patents and rewarding a royalty receiving party that has not invested in patents. There is no commercial logic to this position and, viewed from Novartis's perspective, such a bargain would have been illogical given that the percentage royalties it pays are orders of magnitude higher than the royalties that Incyte pays.

II. Incyte Does Not Have "Regulatory Exclusivity" Over JAKAFI®

There is no dispute that, as Novartis asserts (Opp. 17), JAKAFI® retains ODE for two of its FDA-approved indications. But that fact is irrelevant, because once ODE expired for the MF indication, Incyte lost the regulatory "ability to exclude" third-party Commercialization of a ruxolitinib drug labeled for the treatment of MF (but not PV or GVHD). *See* Mot. 17-24.[5]

Novartis's assertion (Opp. 17-18) that "Royalties Pertain to Licensed Products, Not Indications" proves Incyte's position is the correct one. Section 8.3(c) uses the term Regulatory Exclusivity to make clear that the step-down could occur once the Commercializing party no longer had the regulatory ability to exclude third-party Commercialization of a competing product.

[5] Novartis notes (Opp. 17) that a separate type of exclusivity, New Clinical Investigation ("NCI") exclusivity, applies to the GVHD. This is of no consequence: Incyte no longer has the ability to exclude third party Commercialization labeled for MF, which has neither ODE nor NCI protection.

That happened for Incyte once ODE expired for the MF indication for JAKAFI®—the ***product*** no longer has exclusivity granted by FDA regulations, because a competitor labeled for MF is not excluded, even if certain ***indications*** remain protected by ODE or NCI exclusivities. Novartis points out (Opp. 19) that elsewhere in the contract, Section 8.2, the parties refer to milestones obtained by-indication, rather than by-product. Incyte agrees with Novartis (*see* Opp. fn. 14) that the Court must give meaning to the parties' choice to differentiate between indications and products. *See Int'l Fid. Ins. Co. v. Cty. of Rockland*, 98 F. Supp. 2d 400, 412 (S.D.N.Y. 2000) ("Sophisticated lawyers … must be presumed to know how to use parallel construction and identical wording to impart identical meaning when they intend to do so, and how to use different words and construction to establish distinctions in meaning."). But doing so here confirms Incyte's position: even if Incyte retains regulatory rights to exclude for the GHVD and PV indications, those rights do not give it a regulatory ability to exclude competition as to the product JAKAFI®.

Novartis's premise (Opp. 18) that the parties did not agree "that the loss of one regulatory exclusivity for one medical condition would amount to the loss of all Regulatory Exclusivity for the entire drug product" is circular logic. The very issue in dispute is whether it was the parties' intent that expiration of exclusivity for one indication ends Regulatory Exclusivity—as that term was defined in the contract. Novartis's position that it does not contradicts the contract language. "Regulatory Exclusivity" is defined as "the ability to exclude Third Parties from Commercializing a Licensed Product in a country," Agreement § 1.101, and "Commercializing" means "any activities directed to obtaining pricing and/or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, and/or selling a product." *Id.* § 1.19. A third party marketing a generic version of ruxolitinib drug labeled only for the MF indication remains an activity directed to selling a competing product qualifying as Commercialization. With ODE for

MF expired, Incyte does not have any rights under FDA regulations giving it the "ability to exclude" that third-party Commercialization.

Novartis's contrast (Opp. 20 & n.13) of the Agreement's use of "any" to mean "at least one" to its use of "all" to mean "every one" elsewhere (*e.g.*, Section 1.86 defines "Patent Rights" as "all patents…") underscores the point that a third party engages in Commercialization if it conducts "any"—*i.e.*, any one—of the activities enumerated in the definition, even if it does not conduct "all" such activities. It follows, therefore, that Incyte does not have the "ability to exclude" third parties from Commercialization unless it has the ability to block third parties from conducting all activities constituting Commercialization, for all three indications. Following the expiration of ODE for the MF indication, Incyte no longer has the "ability to exclude" a third party from Commercializing a generic version of ruxolitinib because there no longer is any regulatory barrier preventing a third party from marketing the drug for MF and from conducting activities constituting Commercialization in so doing. Likewise, Novartis's reliance on dictionaries defining "any" as "few," "some," "one or more," or a "small" quantity to argue (Opp 21) that "the parties used 'any' before 'activities' in the term Commercialize' to indicate that one sales or marketing activity … would be enough to qualify as Commercializing" backfires. It shows that a third party's marketing ruxolitinib with a "skinny label" for just MF would "qualify as Commercializing."[6]

Novartis is wrong to argue that Incyte's arguments for dismissal rely on speculation outside the Complaint. Incyte cited the IQVIA Institute report not to raise any factual dispute, but solely to expound the legal principles that apply to drugs with multiple indications with ODEs. Mot. 19.

[6] Novartis's cite to *Nixon v. Missouri Mun. League* in arguing the word "any" has multiple meanings is a red herring. That a word may have multiple uses does not create an ambiguity in a contract where, as here, its meaning is clear in context. *See* Mot 20 n.9 (citing *Collins v. Harrison-Bode*, 303 F.3d 429, 433 (2d Cir. 2002) (quoting *Kass v. Kass*, 91 N.Y.2d 554, 566 (1998)).

Novartis contends the report supports its position by stating that where a drug has multiple indications with ODE, expiration for one may leave "some level of market exclusivity." To the contrary, that statement reinforces that Incyte no longer has Regulatory Exclusivity—i.e., market exclusivity for the ***product***—because it can exclude for only "some" indications, but not for all.

Nor is there anything speculative, as Novartis argues (Opp. 23), about Incyte's prior discussion (Mot. 21-22) of skinny labeling. Incyte's point—that third parties are no longer subject to a regulatory barrier to Commercialization for MF—does not rely on any hypothetical as to whether skinny labeling "may or may not" happen (Opp. 23). The point is that applicable FDA law, which Incyte cited, allows skinny labeling, and so Incyte's regulatory "ability to exclude"—i.e., Regulatory Exclusivity—ended for JAKAFI® with the expiry of the MF indication's ODE.

III. Incyte's Position And The Contract Text Are Commercially Reasonable

Novartis asserts (Opp. 24-25) that adhering to the step-down violates "commercial logic." But "an inquiry into commercial reasonableness is only warranted where a contract is ambiguous," *Int'l Techs. Mktg., Inc. v. Verint Sys., Ltd.*, 157 F. Supp. 3d 352, 364 (S.D.N.Y. 2016), which isn't true here. Regardless, Novartis's notions of what "commercial logic" requires are false and distorts the value of the disputed royalty in terms of the economics of the agreement overall. In reality the agreement is valuable to Novartis even under the Incyte interpretation.

Novartis contends that the parties "agreed to share in the economic success" of ruxolitinib, but that purpose is served with or without the step-down: The parties still collaborate and sell ruxolitinib across the world—to both parties' benefit—and Novartis has received and still receives royalties on U.S. sales, just at a different rate now. Novartis downplays its huge profits from sales abroad as a mere "distraction" (Opp. 10 n.5), but that position contradicts Novartis's own argument that JAKAFI's commercial success in the U.S. is relevant to the contract's proper interpretation. Should the Court find any relevance in the parties' respective profits, it should take note that

Novartis will continue to profit for many years with or without the full royalty it claims is its right.

Novartis is incorrect that "full royalties are due while the Licensed Product enjoys a strong market position," or that it "defies reason" to apply the step-down because Section 8.3(c) is "geared to market deterioration." (Opp. 24.) Such inferences do not follow from the fact that the Agreement contemplates collaboration. What is apparent from the text of the Agreement is that it contemplates two distinct triggers for the step-down. Section 8.3(c)(B) triggers the step-down when "Generic Competition exists"—a condition that is, as Novartis says (Opp. 24), "geared to market deterioration." But the parties agree that Subpart (B) of the step-down provision is not in effect. This dispute is about Subpart (A), which hinges on whether "in a specific country the Licensed Product is neither Covered by a Valid Claim of Licensed Patent Rights nor is such Licensed Product subject to Regulatory Exclusivity." These conditions depend not on whether the U.S. market for JAKAFI® is "strong," but on whether patent rights Novartis could have licensed to Incyte, for example, new formulations, new indications, new combination therapies, which as it turned out, there were none, and the Regulatory Exclusivity JAKAFI® once had, remain in effect. They do not, and so the step-down is in effect. That is a reasonable result given that Subpart (A) is geared toward expiry of intellectual property rights, not "market position."

CONCLUSION

The Court should grant Incyte's motion to dismiss the Complaint in its entirety.

DATED: June 1, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2020, I electronically filed the foregoing with the Clerk of the Court using CM/ECF. I also certify that the foregoing is being served this day on all counsel of record via transmission of Notice of Electronic Filing generated by CM/ECF.

/s/ Richard I. Werder, Jr.
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